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| EXAMINER | |
|---|---|
| MCCLAIN-COLEMAN, TYNESHA L. | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 4132 | |

| NOTIFICATION DATE | DELIVERY MODE |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DCIPDocket@arentfox.com
IPMatters@arentfox.com
Patent_Mail@arentfox.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/530,492 | POURU ET AL. | |
| | Examiner | Art Unit | |
| | TYNESHA MCCLAIN-COLEMAN | 4132 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20050406*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Comment [m1]: Make sure all claims are accounted for. Some claims have not been rejected over prior art.

Comment [tm2]: All claims have been accounted for. See email.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 4-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 2, 4, 5, and 8 are rejected under 35 U.S.C. 102(a) as being anticipated by *Wester et al*. WO02/082929 (hereinafter "*Wester*").

6. With respect to claims 1 and 4, *Wester* discloses a composition comprising combinations of dietary fibres and plant sterols (page 3, lines 3-4). The term plant sterol refers to both sterols and saturated sterols i.e. stanols either in their free form or esterified with e.g. fatty acids (page 5, lines 3-4). One example of the composition included fruit muesli containing stanol ester and β-glucan (Example 12, page 20). The fruit muesli contained 2.5g of plant sterol ester, and the total weight of the composition was 60g (including the oat flakes, oat bran concentrate, plant stanol ester, oat bran, sugar, rice crispy, vegetable oil, syrup, salt, and fruit mixture). Thus, the product contained about 4.17 weight percent of plant stanol ester, which falls within the claimed range.

7. Regarding claims 2 and 5, the fruit muesli composition mentioned above also contains 6.0g of sugar. As a result, the total composition included 10% sugar by weight, which falls within the claimed range (Example 12, page 20).

8. With respect to claim 8, the fruit muesli composition mentioned above in example 12 also contains 8.3% β-glucan, a soluable fibre, which falls within the claimed range of 3.5 to 60 weight-% of dietary fibre (Example 12, page 20).

9. Claims 1, 3, and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by *Plank et al*. US 2003/0235643 A1 (hereinafter "*Plank*").

10. Regarding claims 1, 3, and 11, *Plank* discloses a food intermediate containing phytosteryl esters (fatty acid derivatives of phytosterols) complex and the method used to create the food intermediate (paragraph [0002]). The phytosterols and fatty acid derivatives thereof are bound in a complex with polysaccharide by heating the phytosterol/phytosteryl ester in a mixture containing polysaccharide. The complex may then be dried and is then added to the flour that is then processed to dough (paragraph [0039]). Between 1 and 10 grams of sterols are provided per serving in the matrix and more preferable, about 2-6 grams per 30 gram serving, or approximately 10 to 20% by weight (paragraph [0044]). Ready to eat (RTE) cereal in the form of flakes are created by using a cereal dough as prepared above (paragraph [0044], claims 1 and 11). The cereal dough is formed into pellets, and then the pellets are formed into wet flakes. The wet cereal flakes are toasted or heated (paragraph [0045], claim 3).

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 6, 7, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Wester et al.* WO02/082929 (hereinafter "*Wester*").

14. With regards to claim 6, *Wester* discloses an example of a cereal product containing β-glucan and stanol fatty acid ester (Example 7, page 17). The muesli mixture consisted of oat flake, fibre-rich oat bran, rye flake, wheat germ, brown sugar, sugar syrup, salt, apple flake, raisin, hazel nut, vegetable fat, and stanol fatty acid ester. The composition has a total mass of 990g, and the weight percent of stanol fatty acid ester present in the composition is about 2% (20g of stanol fatty acid ester was used). Since the stanol fatty acid ester is the only plant sterol ester used in this example, the

plant sterol ester comprises 100 percent by weight of stanol fatty acid ester, which falls within the claimed range.

15. With respect to claim 7, *Wester* discloses another cereal composition comprising combinations of dietary fibres and plant sterols (page 3, lines 3-4). A fermented yoghurt-like cereal product was listed as an example of this composition (Example 13, page 20). The total weight of the composition was 100g, and there were 2g of plant sterol fatty acid ester present. The weight percent of plant sterol fatty acid ester in the cereal product would be 2%. Since this is the only plant sterol ester present in this composition, the plant sterol ester used contains 100% of sterol fatty acid ester, which falls within the claimed range of 0-100 weight percent.

16. However, *Wester* does not disclose that the cereal composition contains 2.2-25 weight-% plant sterol esters.

17. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the amount of plant sterol and stanol fatty acid esters used by *Wester* from 2g to 2.2g.

18. One having ordinary skill in the art would have been motivated to do this in order to ensure that the recommended daily intake of plant sterols (1.6-3g) is achieved. Since the content of plant sterols in the food product can range from 0.05 to 12.5g, increasing the amount of plant sterol and stanol fatty acid esters in the cereal composition to 2.2g would fall within the range of the recommended daily intake of plant sterols.

19. Regarding claim 9, *Wester* discloses a composition comprising combinations of dietary fibres and plant sterols (page 3, lines 3-4). The term plant sterol refers to both

sterols and saturated sterols i.e. stanols either in their free form or esterified with e.g. fatty acids (page 5, lines 3-4). One example of the composition included fruit muesli containing stanol ester and β-glucan (Example 12, page 20). The fruit muesli contained 2.5g of plant sterol ester, and the total weight of the composition was 60g (including the oat flakes, oat bran concentrate, plant stanol ester, oat bran, sugar, rice crispy, vegetable oil, syrup, salt, and fruit mixture). Thus, the product contained about 4.17 weight percent of plant stanol ester, which falls within the claimed range.

20. The fruit muesli composition mentioned above also contains 6.0g of sugar. As a result, the total composition included 10% sugar by weight (Example 12, page 20). However, this particular example does not disclose that the cereal comprises 17.5 to 50 weight-% sugar.

21. In another example, *Wester* discloses a muesli mixture containing β-glucan and stanol fatty acid ester (Example 7, page 17). This mixture contains 170g of sugar (100g brown sugar and 70g of sugar syrup), which is about 17.2% weight of sugar present in the mixture.

22. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the amount of sugar present in example 12 with the amount of sugar listed in example 7. It is also obvious to consider sugar from the fruit as additional sources of sugar.

23. One having ordinary skill in the art would have been motivated to do this because the addition of sugar enhances the flavor of the cereal making it more appealing to consume.

24. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Wester et al.* WO02/082929 (hereinafter "*Wester*") in view of *Plank et al.* US 2003/0235643 A1 (hereinafter "*Plank*"). *Wester* is relied upon as above with the rejection of claims 1 and 9.

25. Regarding claim 10, *Wester* discloses a muesli mixture containing plant sterols, β-glucan, and sugar (Example 7, page 17 and Example 12, page 20). However, *Wester* does not disclose that the cereal mixture has been puffed and/or extruded.

26. *Plank* discloses a food intermediate containing phytosteryl esters (fatty acid derivatives of phytosterols) complex and the method used to create the food intermediate (paragraph [0002]). The phytosterols and fatty acid derivatives thereof are bound in a complex with polysaccharide by heating the phytosterol/phytosteryl ester in a mixture containing polysaccharide. The complex may then be dried and is then added to the flour that is then processed to dough (paragraph [0039]). Between 1 and 10 grams of sterols are provided per serving in the matrix and more preferable, about 2-6 grams per 30 gram serving, or approximately 10 to 20% by weight (paragraph [0044]). Ready to eat (RTE) cereal in the form of flakes are created by using a cereal dough as prepared above (paragraph [0044]). The cereal dough is formed into pellets, and then the pellets are formed into wet flakes by passing the pellets through chilled roller and then toasting or heating the wet cereal flakes (paragraph [0045]), claim 10).

27. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the plant sterol ester source used by *Wester* with that of *Plank*.

28. One having ordinary skill in the art would have been motivated to incorporate the flakes produced by *Plank* into the muesli mixture disclosed by *Wester* because the flakes provide more texture and an additional variety of flakes to the muesli mixture.

***Conclusion***

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to TYNESHA MCCLAIN-COLEMAN whose telephone number is (571)270-1153. The examiner can normally be reached on Monday - Thursday 7:30AM - 5:00PM Eastern Time.

30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael LaVilla can be reached on (571)272-1539. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

31. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

32. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like

assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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